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| 10/536,550 | 07/25/2005 | Helen Sang | 08830-0341US1 | 9903 |

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| EXAMINER | |
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| WILSON, MICHAEL C | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/536,550 | SANG ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Wilson | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-26-05&duplicate on1-25-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Claims 12 and 13 are canceled. Claims 1-11 and 14-23 remain pending.

Applicant's election with traverse of Group I, claims 1-6, 9-11, 14-17 and 19-23 in the reply filed on 2-21-07 is acknowledged. The traversal is on the ground(s) that Vick does not teach using lentiviral vectors for transfection of PGCs. Applicants' argument is not persuasive. Vick states, "Two defective retroviruses were used to transform PGCs" (pg 180, line 16). In the NLB experiments, lines zero (White Leghorn) "PGCs were transfected with the defective retroviruses, and these cells were then introduced into Rhode Island Red recipient embryos" (pg 180, second full paragraph). Applicants argue the transduction efficiency of Vick is not satisfactory. Applicants' argument is not persuasive. The claims do not require any particular transduction efficiency.

Upon reconsideration, however, claims 7 and 8, Group II, have been recombined with Group I.

Claim 18 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2-21-07.

Claims 1-11, 14-17 and 19-23 are under consideration.

### *Specification*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. **The sequences on pg 25, lines 14-15, do not have SEQ ID NOs.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

***Priority***

Support for "tissue-specific" expression in new claim 19 is found on pg 38, lines 27-31, which states The size of transgenes that can be incorporated in lentiviral vectors is limited and therefore some tissue-specific regulatory sequences may be too big for use in these vectors."

Support for expression in egg white or yolk in new claim 20 is found on pg 16, lines 29-31.

Support for new claims 21-24 are found in original claims 15-17 of WO04/047531 (Parent Application PCT/GB03/05191).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 14-17 and 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a introducing a lentivirus encoding a

protein to a chicken embryo and obtaining a transgenic avian that expresses the protein in egg white or yolk does not reasonably provide enablement for making any species of transgenic avian or making a transgenic chicken by transfecting embryonic chicken cells in vitro. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is drawn to the production of transgenic avians, the method comprising the step of using a lentivirus vector system to deliver exogenous genetic material to avian embryonic cells or cells of the testes. Claims 2-6, 15-17 are dependent upon claim 1.

Claim 9 is drawn to a method for the production of an heterologous protein in an avian, the method comprising the step of delivering genetic material encoding the protein within a lentivirus vector construct to avian embryonic cells so as to create a transgenic avian which expresses the genetic material in its tissues. Claims 10, 11, 14 and 19-23 are dependent upon claim 9.

Claims 1-6, 9-11, 14-17 and 19-23 encompass making any species of transgenic avian and making transgenic chickens by transfecting embryonic chicken cells in vitro.

MacArthur (US Patent 6,825,396 filed April 18, 1997) introduced a retroviral vector encoding a protein operably linked to the ovalbumin promoter and an SV40 enhancer beneath a chicken blastoderm and obtained a chimeric chicken that expressed the protein in egg white (col. 15, lines 1-12; claim 1). The promoter directs

expression to the oviduct (col. 3, lines 1-3), and the protein is isolated from the egg (col. 3, lines 29-32).

Vick (Proc. R. Soc. Lond., 1993, Vol. 251, pg 179-182) isolated stage XI PGCs from chickens, transduced them with retrovirus encoding the neomycin resistance gene (Neo) and LacZ under the control of long terminal repeats (LTR), and immediately injected them into the vasculature of Stage 15 chick embryos to obtain germline transmission and expression of LacZ.

Allioli (Developmental Biol., 1994, Vol. 165, pg 30-37) expressed exogenous DNA in PGCs transfected with a retroviral vector and cultured for 2 days *in vitro* (pg 36, col. 1, lines 1-5).

Thoroval (Transgenic Research, 1995, Vol. 4, pg 369-376) injected AVL retroviral vectors encoding the neomycin resistance gene (Neo) and LacZ into the subgerminal cavity of an avian embryo in a freshly laid egg to obtain germline transmission of a transgene and expression of Neo and LacZ.

Naito (March 31 - April 5, 1996, 6$^{th}$ International Symposium on avian endocrinology, "Expression of exogenous DNA in embryonic gonads by transferring primordial germ cells transfected in vitro", pg 69-73) isolated PGCs from the blood of a chicken embryo, transfected the chicken PGCs with a plasmid encoding LacZ under the control of the chicken $\beta$-actin promoter *in vitro,* transferred the PGCs to a recipient chick embryo, obtained a chimeric chicken and obtained expression of the transgene in gonads of the chimeric chicken. Naito did not teach the plasmid or PGCs were passed on to its offspring because Naito did not teach making offspring.

Ronfort (Transgenic Animals: Generation and Use. Houdebine LM (ed.), Harwood Academic Publishers, The Netherlands, pg 83-94) summarized the use of retroviral vectors for gene transfer into bird embryos.

Naito (1998, J. Reproduction and Fertility, Vol. 113, pg 137-143) later determined the transgene was lost during embryonic development because it was episomal (see abstract). Therefore, Naito 1996 did not teach how to make a chimeric chicken that passed the plasmid on to its offspring or how to express a transgene in a specific tissue of a chimeric chicken.

Pain (Development, 1996, Vol. 122, pg 2339-2348) obtained ES cells from Stage X embryos within a mixed population of PGCs and cells that provide germline and somatic cell transmission. Pain taught marker proteins found on the mixed population of cells (pg 2345, col. 2).

Sayegh (Veterinary Immunology and Immunopathology, Dec. 15, 1999, Vol. 72, pg 31-37) introduced a retroviral vector encoding a truncated antibody receptor into chickens "somatically" and express the receptor in the bursa at hatch (pg 32, 2nd full ¶, lines 2-5 and 16-18; ¶ bridging pg 33-34). Sayegh did not deliver the retrovirus to avian embryonic cells or cells of the testes.

Zandong (Transgenic Research, February 2002, Vol. 11, No. 1, pp. 85) isolated gonad PGCs from 5.5-day-old chicken embryos and cultured them on gonad stroma cells with addition of 5 ng/ml SCF and 10 ng/ml LIF. They proliferated for 10 days in culture. The colony appeared to be positive after PAS staining. A 1.2 kb fragment of the chicken ovalbumin gene promoter sequence cloned by PCR was used to replaced

and second exons including signal sequence also have been cloned and inserted into the multiple clone sites upstream to the EGFP gene in modified pEGFP. Cultured CEFs were transfected with the constructed vector by lipofectin (Gibco) and showed faint fluorescence after 24 h culture. Cultured CEFs (DMEM/F12+10%FBS) were transfected with 4$\mu$g plasmid pEGFP-C1 (Clontech) by lipofectin (Gibco), followed by electroporation under 200 voltage. The pEGFP-C1 mixed with lipofectin (1:2.5) were microinjected into chicken blastoderms (stage X) *in vivo*, followed by electroporation under 10 v, then the eggs were hatched for 72 h. GFP expression was examined under inverted fluorescent microscope. Transfection efficiency was improved by lipofection and electroporation. The same result was observed in early chicken embryos. Zandong suggested performing further research focused on transfecting PGCs with the constructed vector and subsequently producing transgenic chickens.

Harvey (Nature Biotech., April 2002, Vol. 19, pg 396-399) made transgenic chickens by injecting a NLB retroviral vector encoding $\beta$-lactamase operably linked to the CMV promoter into the subgerminal cavity of stage X embryos. The chicks expressed and secreted exogenous protein in egg white (pg 397, col. 2, 2$^{nd}$ full ¶).

Petitte (J. Poultry Sci., 4$^{th}$ quarter of 2002, Vol. 39, No. 4, pg 205-228) discusses cells of the avian germline and summarizes strategies for making transgenic chickens. Retroviral gene transfer of chick embryos is frequently employed for the induction of ectopic expression of exogenous genes and has become one of the techniques to examine gene function during chicken embryo development (Iba 2000). Their use in the development of transgenic poultry has been less widespread mainly because of the

need for a fully equipped research lab coupled with extensive hatching, rearing and egg production facilities. Nevertheless, retroviral gene transfer continues to be the most successful method of producing transgenic poultry (pg 221, lines 3-9). Petitte summarizes the use of retroviral vectors to make transgenic chickens in the paragraph bridging pg 213-214.

Ivarie (Trends in Biotechnology, Jan. 2003, Vol. 21, pg 14-19) taught that because of the complex process by which a bird makes and lays eggs, transgenic procedures for birds have lagged far behind those of other organisms. Ivarie cites Pain who taught long-term culture of non-transfected, blastodermal cells that provided germline transmission; however, no transgenic birds have been made using ES cells or PGCs transfected in culture. The biggest obstacle to overcome in making transgenic birds using transfected PGCs is the loss of germline competence during culture of transfected PGCs (pg 14, col. 2, 3rd full ¶, 1st sentence; pg 17, col. 1, 2nd full ¶, last two sentences; pg 17, sentence bridging col. 1-2; pg 17, col. 2, last sentence). Thus, a transgenic avian could not be made by transfecting PGCs and maintaining the transfected PGCs in culture.

Naito (Animal Sci. J., June 2003, Vol. 74, pg 157-168) summarized the manipulation of PGCs and confirms transgenic avians had not been made by transfecting PGCs and maintaining the cells in culture (pg 163). It is noted that Naito states, "for practical applications, however, non-viral methods for DNA transfer into chickens are preferable" (pg 162, col. 1, last 5 lines).

Rapp (Transgenic Res., Oct. 2003, Vol. 12, pg 569-575) injected retroviral particles encoding interferon (IFN) under the control of the CMV promoter into the subgerminal cavity of chicken embryos (pg 570, col. 2, "Generation of transgenic chickens"). IFN expression was detected in egg white of hemizygous G2 hens (pg 573, col. 1, lines 1-10).

The specification teaches, "a specific promoter may be used with a lentiviral vector construct to result in tissue specific expression of the DNA coding sequence. This may include promoters such as CMV, PCAGGS or any promoter based upon a protein usually expressed in an avian egg; such as ovalbumin, lysozyme, ovotransferrin, ovomucoid, ovostatin, riboflavin-binding protein or avidin" (pg 17, lines 15-22).

The specification teaches making a transgenic chicken using a retroviral vector encoding LacZ operably linked to the human CMV, "an enhancer/promoter generally described as functioning ubiquitously in many cell types (sentence bridging pg 37-38). Expression was predominantly in the pancreas but was found in most tissues (pg 38, lines 9-12).

The specification mentions a third generation EIAV vector pONY8.4 (pg 38, line 13-14). The specification states "expression was not detected in a small number of pONY8.4GCZ transgenic birds" (pg 38, lines 17-19). The specification states the "expression pattern seen in G1 birds in maintained after germ line transmission to G2. These results indicate that transgene-specific expression, from transgenes introduced using lentiviral vectors, is maintained after germline transmission" (pg 38, lines 23-26).

However, the specification does not teach the structure of pONY8.4GCZ transgenic birds

The specification states, "the size of transgenes that can be incorporated in lentiviral vectors is limited and therefore some tissue-specific regulatory sequences may be too big for use in these vectors (pg 38, lines 27-31).

Applicants acknowledge that Rapp (2003, cited above) taught using ALV vectors to generate a transgenic chicken that expresses accumulates protein in egg white on pg 39, lines 24-28. Applicants have provided no more than reference to Rapp (2003) for those of skill to express heterologous protein in the egg white or yolk.

The specification does not overcome the teachings described by Naito (1998) or Ivarie to make transgenic chickens by transfecting embryonic chicken cells in vitro. Without such guidance, it would have required one of skill undue experimentation to determine how to overcome such unpredictability. Thus, the specification does not enable those of skill to make transgenic chickens by transfecting embryonic chicken cells in vitro as encompassed by the claims.

The specification does not enable obtaining any species of avian embryonic cells or making any species of transgenic avian as broadly claimed. The number of species within the genus of avian is immense compared to the one species of chickens described by applicants (see table of Bird Classification/Families of the Eastern US Birds). The specification does not correlate the structure of chicken embryonic cells to any other avian species and does not correlate the stages of chick embryos to other avian species. Without such guidance and in view of the absence of transgenic avian

species in the art or the specification, it would have required one of skill undue experimentation to determine how to make a transgenic avian in species other than chickens. In a parallel example, the ability to make transgenic rats was elusive for 15 years after scientists first made transgenic mice despite the similarities in mice and rat embryos and reproductive systems (Proudman, 2001, "The quest for transgenic poultry: birds are not mice with feathers" Biotechnology in Animal Husbandry, Vol. 5, Kluwer Academic Publishers, pg 283-299; pg 284, lines 1-6). 15 years of research to determine how to achieve germline transmission in avian species other than chickens is undue. Applicants have not provided the blaze marks for one of skill to determine which of the numerous methods of making transgenic chickens will be successful in other avian species. It would have required those of skill to think outside of the realm of transgenic chickens to obtain embryonic cells in other avian species, which is more than "routine experimentation" or trial and error. Therefore, the claims should be limited to chicken cells and producing chimeric chickens.

Claims 7 and 8 are included because they are drawn to any transgenic avian made by the method of claim 1.

***Indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 14-17 and 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "comprising the step of using" in claim 1 is indefinite because it does not clearly set forth the method step. "Delivering a lentivirus comprising exogenous..." would be clear.

Claim 2 is indefinite because it is unclear how the "lentivirus transgene construct in a form which is capable of being delivered to and integrated with the genome of avian embryonic cells or cells of the testes" further limits claim 1 because lentiviruses integrate into the genome of cells. It cannot be determined what embodiments from claim 1 are being excluded in claim 2.

The phrase "into the contents of an opened egg" in claim 3 is unclear because it does not clearly refer to the "subgerminal cavity" of an "avian embryo" or to the "contents" comprising an avian embryo. Accordingly, the phrase "which is then allowed to develop" should clearly refer to an avian embryo and not an egg as currently written.

The metes and bounds of the "sub-blastodermal cavity of an egg" in claim 4 are unclear. It cannot be determined how the "sub-blastodermal cavity" is different than the "subgermline cavity" in claim 3.

The metes and bounds of what applicants consider "high efficiency" in claim 5 cannot be determined. The phrase is relative and subjective according to each investigator.

Claim 7 is indefinite because it does not clearly refer to the method of claim 1.

Claim 8 is indefinite because it does not further limit the transgenic avian of claim 7. "A transgenic avian and subsequent transgenic offspring produced as the offspring of a transgenic avian" does not make sense.

The phrase "so that the translated protein" in claim 10 lacks antecedent basis and does not clearly refer back to the "gene." The claim should at least imply the translated protein came from the gene.

The abbreviations in claims 15 and 21 should be spelled out before being abbreviated. In particular, the term "DIV" does not have a definition in the specification or the art; therefore, the meaning is unclear.

The phrase "suitable enhancer promoter... ...for subsequent production of protein" in claims 16 and 22 is unclear. Suitable is a relative term and subjective to each investigator. The phrase enhancer promoter does not have an art recognized meaning and is not defined in the specification. The phrase "subsequent production of protein" does not make sense. Overall, the metes and bounds of the structure and function of the regulatory element cannot be determined.

Claims 17 and 23 are indefinite because the phrase "particles of the vector construct" does not make sense. While a lentivirus can be a viral particle, the construct is not a particle. It is unclear whether the claim is limiting a function of the vector or that viral particles are being delivered to avian embryonic cells. In addition, it is not clear that viral DNA in an envelope is a "vector with an envelope" as claimed.

Claim 19 is indefinite because the metes and bounds of "tissue-specific" are unclear. It is unclear what level of specificity is required as the metes and bounds are not defined in the specification and vary in the art.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-11, 14, 16, 17, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by MacArthur (US Patent 6,825,396 filed April 18, 1997). MacArthur introduced a retroviral vector encoding a protein operably linked to the ovalbumin promoter and an SV40 enhancer beneath a chicken blastoderm and obtained a chimeric chicken that expressed the protein in egg white (col. 15, lines 1-12; claim 1). The promoter directs expression to the oviduct (col. 3, lines 1-3), and the protein is isolated from the egg (col. 3, lines 29-32). Expression can also under the control of promoters that provide expression in egg yolk (col. 7, line 41-56).

Claims 1, 2, 5, 6-9, 16, 17, 19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Vick (Proc. R. Soc. Lond., 1993, Vol. 251, pg 179-182). Vick isolated stage XI PGCs from chickens, transduced them with retrovirus encoding the neomycin resistance gene (Neo) and LacZ under the control of long terminal repeats (LTR), and immediately injected them into the vasculature of Stage 15 chick embryos to obtain germline transmission and expression of LacZ. The specification teaches tissue-specific promoters include CMV, pCAGGS or any promoter that is usually expressed in an avian egg (pg 17, lines 15-22). CMV is a viral constitutive enhancer promoter (pg 20, lines 7-8). RAV-2 regulating sequences express protein in "specific tissues" (claim 14), are a "suitable enhancer promoter element for subsequent production of protein" (claim 16) and provide "tissue-specific" expression (claim 19) because they express the exogenous protein in chicken tissue and because the definition on pg 17 encompasses any promoter that provides expression. The limitations in claims 14, 16 and 19 do not distinguish the structure or function of the promoter over the RAV-2 regulating sequences taught by Vick.

Claims 1-9, 14, 16, 17, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Thoroval (Transgenic Research, 1995, Vol. 4, pg 369-376). Thoroval injected AVL retroviral vectors encoding the neomycin resistance gene (Neo) and LacZ both under the control of RAV-2 regulating sequences into the subgerminal cavity of an avian embryo in a freshly laid egg to obtain germline transmission of a transgene and expression of Neo and LacZ (pg 370, col. 2, "Retroviral vector", "Infection of embryos"; pg 371, col. 2, "Analysis of DNA from hatched..."). RAV-2 regulating

sequences meet the limitations of claims 14, 16 and 19 for reasons in the paragraph above.

Claims 1-11, 14, 16, 17, 19, 20, 22 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Harvey (Nature Biotech., April 2002, Vol. 19, pg 396-399). Harvey made transgenic chickens by injecting a NLB retroviral vector encoding β-lactamase operably linked to the CMV promoter into the subgerminal cavity of stage X embryos. The chicks expressed and secreted exogenous protein in egg white (pg 397, col. 2, 2nd full ¶). The protein was isolated from the egg along with the egg white (pg 399, col. 1, last two paragraphs). CMV is a tissue specific promoter enhancer (pg 17, line 18; pg 20, line 8).

Claims 1, 2, 5-9, 15-17 and 21-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Baltimore (US Patent Application Publication US 2003/0101471 A1, filed Sept. 13, 2002, published May 29, 2003). This rejection assumes priority document 0227645.9 filed 11-27-02 does not teach using EIAV, HIV, SIV, DIV or FIV as in claims 15 and 21. Without evidence to the contrary, the effective filing date of claims 15 and 21 is 11-27-03, the filing date of priority document PCT/GB03/05191. Baltimore teaches making transgenic chickens by injecting lentiviral particles into chicken embryos (pg 13, Example 2). The lentiviral particles comprise a nucleic acid sequence encoding a protein operably linked to a promoter. The lentivirus is HIV, equine infectious anemia virus (EIAV), FIV, BIV or SIV (pg 4, paragraph 55).

***Conclusion***

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER